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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,444	02/13/2001	Heather A. Bartholf	CRD0887	9864

7590                    02/28/2003

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EXAMINER
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SNOW, BRUCE EDWARD

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 02/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/782,444	BARTHOLF ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Bruce E Snow	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 December 2002.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 17-21 is/are allowed.
- 6) Claim(s) 1-16 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Allowable Subject Matter***

Claims 17-21 are allowed.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6 and 9 are rejected under 35 U.S.C. 102(b) as being **clearly anticipated** by Sullivan (WO 98/23241).

Sullivan teaches a catheter and stent system comprising a clear outer sheath 14 which inherently includes a bonded distal section which covers the stent; an inner shaft 35; stent 18.

Regarding claim 8, "less than about 20" could include zero.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan (WO 98/2341) and further in view of Willard et al (6,309,379).

Sullivan teaches the device as described in the rejection above, however, is silent regarding a radiopaque marker at a distal tip of said enlarged distal section and being made from a formulation containing 20-75 weight percent of a radiopaque agent. (It is noted that Sullivan teaches a proximal sheath marker 42 for the same purpose.)

Willard et al teaches a delivery sheath having a distal sheath marker 66, shown in figure 4, and teaches a radiopaque formulation as claimed. See column 9, lines 13 et seq. It would have been obvious to one having ordinary skill in the art to use the distal marker of Willard et al with the device of Sullivan for a means of visualizing the end of the sheath.

Claims 1, 6, 9, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poncet (5,833,694) in view of Sullivan (WO 98/2341).

Poncet teaches a device comprising an outer sheath 20 having an enlarged distal section containing a self-expanding stent. However, Poncet is silent regarding the enlarged distal section being formed from a relatively clear polymer material. Sullivan teaches using a relatively clear polymer for a stent sheath. It would have been obvious to one having ordinary skill in the art to have utilized the clear polymer of Sullivan for the

sheath of Poncet to enable a visual inspection of the stent. See figure 7 and page 4, lines 19-21 of Sullivan.

Claims 2-5, 7-8, 10-11, 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poncet (5,833,694) and Sullivan (WO 98/2341) and further in view of Willard et al (6,309,379).

Poncet and Sullivan teach the device as described in the rejection above. However, they are silent regarding a radiopaque marker at a distal tip of said enlarged distal section and being made from a formulation containing 20-75 weight percent of a radiopaque agent. (It is noted that Sullivan teaches a proximal sheath marker 42 for the same purpose.)

Willard et al teaches a delivery sheath having a distal sheath marker 66, shown in figure 4, and teaches a radiopaque formulation as claimed. See column 9, lines 13 et seq. It would have been obvious to one having ordinary skill in the art to use the distal marker of Willard et al with the device of Poncet and Sullivan for a means of visualizing the end of the sheath.

### ***Conclusion.***

**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (703) 308-3255. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703)308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



BRUCE SNOW  
PRIMARY EXAMINER

bes  
February 25, 2003